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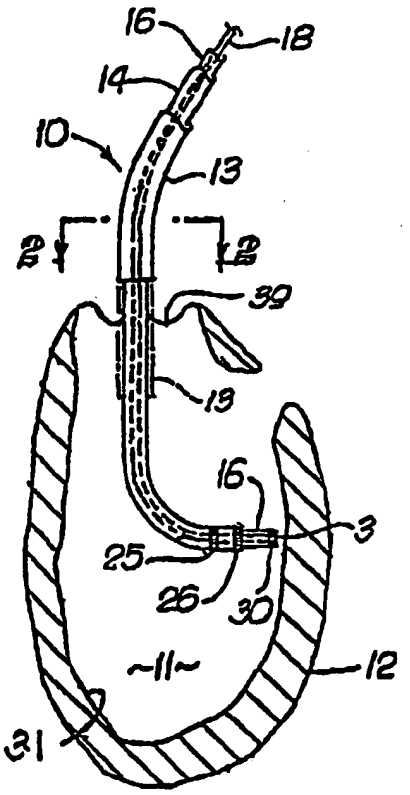
(54) Title: SYSTEM FOR TREATING OR DIAGNOSING HEART TISSUE

(57) Abstract

A system for delivering the distal operative end of a therapeutic or diagnostic device which includes a first delivery catheter, preferably configured to be slidably and rotatably disposed within an inner lumen of a guiding catheter. A second delivery catheter may be slidably disposed within an inner lumen of the first delivery catheter and have an inner lumen configured to slidably receive an elongated therapeutic or diagnostic device such as a channel forming device, e.g. an optical fiber connected to a laser source. The distal extremity of the first delivery catheter is shaped or is shapable within the patient's heart chamber so that longitudinal movement of the first delivery catheter into and out of the inner lumen of the guiding catheter and rotation of the first delivery catheter facilitates the accurate placement of the distal extremity of the therapeutic or diagnostic device at one or more desirable locations within the patient's heart chamber. The second delivery catheter is moved out of the inner lumen of the first or first delivery catheter until the distal end extends out of the distal end of the first delivery catheter and provides a passageway for the therapeutic or diagnostic device to engage the endocardium surface at a perpendicular or near perpendicular orientation. In one embodiment, the distal section of the first delivery catheter is provided with a double bend to facilitate a perpendicular approach to the surface of the endocardium in certain situations.



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SYSTEM FOR TREATING OR DIAGNOSING HEART TISSUE

RELATED APPLICATION

This application is a continuation-in-part of copending application Serial No. 08/438,743, filed on May 10, 1995, entitled DELIVERY SYSTEM AND METHOD FOR MYOCARDIAL REVASCULARIZATION, which is incorporated herein in its entirety.

BACKGROUND OF THE INVENTION

This invention is directed to elongated devices for therapeutic or diagnostic procedures in a wall of a patient's heart, particularly to the treatment of myocardial tissue experiencing ischemic conditions by revascularization of such myocardial tissue.

Myocardial revascularization typically involves formation of one or more channels in a patient's heart wall defining the heart chamber to allow oxygenated blood to flow from the left ventricle of the patient's heart through the endocardium into a patient's ischemic myocardial tissue. The first trials of the revascularization process was made by

Mirhoseini *et al.* See for example the discussions in Lasers in General Surgery (Williams & Wilkins; 1989), pp 216-223. Another early disclosure of this proc dure is found in U.S. Patent 4,658,817 (Hardy). Both of these references describe revascularization procedures which require the chest wall to be opened and which include formation of the revascularization channels through the epicardium, myocardium and endocardium, i.e. the entire heart wall.

Copending application Serial No. 08/078,443, filed on June 15, 1993 (Aita *et al.*), which is incorporated herein in its entirety, describes an intravascular system for myocardial revascularization which is introduced into a peripheral artery and advanced through the patient's arterial system into the left ventricle of the patient's heart. The revascularization channels are formed through the endocardium and into the myocardium from within the left ventricle. This procedure eliminates the need of the prior procedures to open the chest cavity and to penetrate the epicardium in order to form the channel through the endocardium into the myocardium. While the percutaneous method and system for introducing the revascularization device developed by Aita *et al.* was a substantial advance, one of the difficulties in forming revascularization channels from within a patient's left ventricle by means of a percutaneously introduced revascularization system was to accurately direct the distal tip of the channel forming device to a desired region of the patient's endocardium and to maintain the placement of the distal end of the channel forming device against a desired region of the ventricular wall at a proper angle, i.e. perpendicular or near perpendicular to the endocardium, while the heart is beating so that there is no lateral displacement of the operative distal tip of the device which can affect the channel formation within the heart wall.

What has been needed is a system and method for delivering a channel forming device within the patient's heart chamber

which provide for the accurate placement of the operativ end of the channel forming device against a desired region of the endocardium at the desired orientation and the maintenance of the position of the device within the patient's heart chamber while the revascularization channel is being formed and the heart is beating. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to a system and method for delivering an elongated therapeutic or diagnostic device to the interior of a patient's heart chamber which provides access to a wide region of the patient's endocardium and accurately places and effectively holds the operative distal end of the device at a desired location within the patient's heart chamber. A typical device may be used to form a channel into the wall defining the heart chamber or perform other ablation treatments and diagnosis. The system also allows the position of the operative distal end of the device to be readily changed to facilitate performing therapeutic or diagnostic procedures at a plurality of locations within the heart chamber and at a desired orientation with respect to the patient's endocardium.

One presently preferred embodiment of the invention includes a first delivery catheter which has proximal and distal ends, a port in the distal end and an inner lumen extending within the catheter to the port in the distal end. The first delivery catheter is provided with a preshaped distal section, or a distal section which can be deformed or shaped once positioned within the patient's heart chamber. The embodiment also includes a second delivery catheter or sleeve longer than the first delivery catheter which is slidably and preferably rotatably disposed within inner lumen of the first catheter. The second delivery

catheter likewise has proximal and distal nds, a port in the distal nd an inner lumen extending within the second catheter to the port in the distal end. The distal section of the second delivery catheter may be straight, i.e. in line with the main catheter section but it is preferably provided with a preshaped distal section, or a distal section which can be deformed or shaped once positioned within the patient's heart chamber, so as to facilitate directing an elongated therapeutic or diagnostic device slidably disposed within the inner lumen of the second delivery catheter toward the region of the endocardium where the procedure is to be performed. The orientation is preferably perpendicular or near perpendicular with the endocardial surface of the patient's heart wall.

A presently preferred elongated therapeutic or diagnostic device is a laser based optical fiber system for forming channels within the wall of the patient's heart. The optical fiber system which is adapted to emit laser energy from its distal end, is slidably disposed within the inner lumen of the second delivery catheter and is long enough to extend out the distal end of the second delivery catheter to be able to engage tissue of the endocardium while forming the channel or performing other types of procedures.

In a presently preferred embodiment of practicing the method of the invention, the system is introduced into a peripheral artery, such as the femoral artery, and to be advanced through the patient's arterial system until the distal end of the first catheter is disposed within the patient's left ventricle or slightly down stream from the patient's aortic valve in the ascending aorta. The first delivery catheter may be advanced through a previously introduced guiding catheter which has a distal end within the left ventricle or within the ascending aorta or over a previously positioned guidewire or catheter. The second delivery catheter is rotatably and slidably disposed within the inner lumen of the first delivery catheter to facilitate the desired

placement and orientation of the shaped or shapable distal extremity thereof within the left ventricle. Perpendicularity or near perpendicularity of the elongated therapeutic or diagnostic device with respect to th inner endocardial surface of the heart chamber is usually required in order to effectively couple the ablation energy to the tissue. Additionally, such perpendicularity helps to maintain the position of the distal end of the device, particularly a channel forming device, against the tissue to be ablated or removed to form the channel. Otherwise, the operative tip of the therapeutic or diagnostic device tends to move laterally while the heart is beating resulting in mislocation of the channel, or ablated tissue or medical procedure.

Longitudinal and rotational movements of the first and second delivery catheters, particularly when the distal extremity of both are shaped or shapeable when disposed within the patient's heart chamber, provides access to a wide region of the patient's endocardial surface and allows for the accurate placement of the operative end of the therapeutic or diagnostic device within the patient's left ventricle in a number of positions. Extension of the second delivery catheter out the distal end of the first delivery catheter to engage the endocardium of the patient's heart can also ensure effective contact by providing more support to the therapeutic or diagnostic device. The location of the distal end of the therapeutic or diagnostic device within the heart chamber and particularly with respect to the endocardial surface can be detected fluoroscopically by providing a radiopaque marker on the distal end of the device. The use of dye injections out the port in the distal end of second delivery catheter or a radiopaque marker on the distal end of the second delivery catheter, or both may be employed to locate the distal end of the first and second delivery catheters. Other means such as a variety of proximity detectors may be employed to detect contact

b tween the distal end of the therapeutic or diagnostic device or the delivery catheters and the endocardium.

The distal sections of the first and second delivery catheters may be preformed into a desired shape so that they will provide a desired orientation for the delivery system when it extends into the patient's heart chamber. The catheters may also be provided with control lines or other suitable means (e.g. a shape memory or a superelastic NiTi element) to deflect or otherwise shape the distal sections of the catheters once the distal extremity of the delivery system extends into the heart chamber. With the system of the invention, essentially the entire inner surface of the wall defining the patient's heart chamber is accessible to deliver an elongated therapeutic or diagnostic device with a desired orientation. The guiding catheter (if used) and first delivery catheter are both preferably relatively stiff catheters so that the position of the therapeutic or diagnostic device will be maintained during the procedure even though the heart is beating. The functions of the first and second delivery catheters can be combined into a single catheter, if the shape of the distal extremity of such a single catheter is controllable after the distal extremity is disposed within the patient's heart chamber.

In another embodiment, the delivery system has an elongated main section and a distal extremity which extends within the patient's heart chamber which has a double bend. The distal extremity has a proximal portion extending away from the main section at an angle and a distal portion extending away from the proximal portion of the distal extremity at an angle. The proximal portion of the distal extremity extends away from the main catheter section at an angle of about 40° to about 120°, preferably about 60° to about 120°. The distal portion of the distal extremity extends away from the proximal portion at an angle of about 40° to about 120°, preferably about 60° to about 120°.

The length of the proximal portion of the distal extremity may range from about 0.5 to about 3 cm, preferably about 1 to about 2 cm and the length of the distal portion may range from about 0.5 to about 2.5 cm, preferably about 0.5 to about 1.5 cm. In one version of this embodiment the delivery system is in the form of a single catheter and a second version of this embodiment the delivery system has first and second delivery catheters as in the previously discussed embodiments. The orientation of the distal portion in the first version may be in one direction for clockwise rotation of the main portion of the delivery system or in another opposite direction for counter clockwise rotation of the main portion. In a second version of this embodiment, the proximal portion of the delivery system is the distal extremity of the first delivery catheter and the distal portion of the delivery system is the distal section of the second delivery catheter which is slidably disposed within the inner lumen of the first delivery catheter.

A positioning sheath may be disposed within the inner most inner lumen of the delivery system which is extended to the surface of the heart wall, to further support the therapeutic or diagnostic device. However, if the delivery system has two changes in direction the advancement of a positioning sheath may become difficult.

The anatomy of the left ventricle can vary considerably as to dimensions and to shape from patient to patient. As a result, in some instances the channel forming member with the first embodiment may not be able to be directed to the entire region in which channels are to be formed. The shape of the guiding catheter or the first delivery catheter and the orientation thereof within the left ventricle can further complicate placement of the channel forming means or other therapeutic or diagnostic device. However, by providing a second delivery catheter with a shaped distal extremity, as in the second discussed preferred embodiment, the rotation of the first and second delivery catheters will

ensure that the therapeutic or diagnostic can reach all or at the very least a major part of the region in which the device is to be operated.

While forming a passageway through the endocardium into the myocardium of the patient's heart for the purpose of revascularization is of significant interest, the passageway formed into the myocardium may be used for other purposes. For example, therapeutic or diagnostic agents may be introduced into the channel for delivery to the patient's endocardium or myocardium. The therapeutic or diagnostic agent may be incorporated into a biocompatible matrix deposited within the channel for delivery or release over an extended period. When delivering a therapeutic or diagnostic agent to the interior of the channel, the channel forming device may be removed and a catheter with an inner lumen extending the length thereof may be advanced through the inner lumen of the second delivery catheter until the distal end of the catheter extends into the channel formed in the wall of the patient's heart. A therapeutic or diagnostic agent may then be delivered through the inner lumen of the catheter and out a port in the distal end into the channel such as described in copending application Serial No. 08. The drug delivery catheter may be generally a simple elongated flexible tube with an inner lumen extending therein to a port or opening in the distal end of the catheter. The outer dimensions are suitable to provide longitudinal movement of the drug delivery catheter within the second delivery catheter. The distal extremity of the drug delivery catheter is preferably configured to readily fit into the channel formed in the endocardium and myocardium so that delivery of the therapeutic or diagnostic agent well into the channel is ensured.

There is some evidence which tend to support the position that the ablation or trauma of myocardial tissue may, by itself, over the long term enhance or even be a major factor in the revascularization of the myocardium by means of angiogenesis. Thus, other means which

damage myocardial tissue can be the causal factor in revascularization. For example, the laser device may be replace with a RF energy or an ultrasonic energy delivery system which damages myocardial tissue without forming a channel. Similarly, injection of small quantities of chemical ablation media such as ethyl alcohol or phenol may likewise be used for similar results. There is also some evidence that ablation of heart tissue within an ischemic area causing angina or chest pain can cause the denervation of the ischemic tissue which results in the termination of the angina. Such pain relief is by itself a substantial clinical advantage because, without the pain, the patient's can resume normal or near normal activity. This minimizes or eliminates the need for pain medication which frequently is quite debilitating. These and other advantages of the invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view of an embodiment of the delivery system of the invention disposed within the arterial system of a patient with the distal end of the system disposed within the patient's left ventricle.

Fig. 2 is a transverse cross-sectional view of the delivery system shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is an elevational view of the system shown in Fig. 1 with the second delivery catheter extending out of the distal end of the first delivery catheter and the distal end thereof pressed against the endocardial layer.

Fig. 4 is an elevational view of the system shown in Fig. 1 with a channel forming device, in this case an optical fiber, extending

out of the second delivery catheter and into a channel formed by laser energy emitted out the distal end of the optical fiber.

Fig. 5 is a schematic representation of the degrees of orientation of the first delivery catheter within the left ventricle of a patient's heart.

Fig. 6 is longitudinal cross-sectional view of the distal end of the optical laser shown in Fig. 4.

Fig. 7 is a perspective view of an alternative embodiment of the invention.

Fig. 8 is a perspective view of an embodiment which is the mirror image of the embodiment shown in Fig. 7.

Fig. 9 is an enlarged view of the embodiment shown in Fig. 8 with indications of orientations of the distal portions of the embodiment.

Fig. 10 is a elevational view of the distal portion of a channel forming device having an auger on the distal tip.

Fig. 11 is an elevational view of the distal portion of a channel forming device having an abrading member on the distal tip.

Fig. 12 is an elevational view of the distal portion of a channel forming device having a circular cutting blade on the distal tip.

Fig. 13 is an elevational view of the distal portion of a channel forming device having a resistance heated distal tip.

Fig. 14 is an elevational view of the distal portion of a channel forming device having a jet forming aperture in the distal tip.

Fig. 15 is a perspective view of an alternative embodiment of the invention.

Fig. 16 is an elevational view of an alternative distal section of the outer catheter shown in Fig. 15.

Fig. 17 is a transverse cross-sectional view of the outer catheter shown in Fig. 16 taken along the lines 17-17.

Fig. 18 is an elevational view of yet another alternative embodiment of the invention.

Fig. 19 is a transverse cross-sectional view of the embodiment shown in Fig. 18 taken along the lines 19-19.

Fig. 20 illustrates the positioning of the assembly of an embodiment of the invention within the patient's left ventricle with the discharge axis of the first catheter coinciding with the axis of the patient's left ventricle.

Fig. 21 illustrates the distal extremity of the delivery catheter system positioned against a patient's intraventricular septal wall.

Fig. 22 illustrates the position of the assembly similar to that shown in Fig. 21 except that the distal extremity of the delivery catheter system is disposed more centrally within the left ventrical. The accessible region of the patient's endocardium with the delivery system in this position, is shaded.

Fig. 23 depicts the assembly shown in Fig. 15 with the distal extremity of the outer delivery catheter at a large obtuse angle with respect to the main portion of the catheter.

Fig. 24 illustrates the assembly shown in Fig. 23 positioned within a patient's left ventricle to access the apical region of the patient's left ventricle which includes the lower interventricular septum region.

Fig. 25 illustrates the assembly shown in Fig. 23 with the inner catheter rotated about 180° from that shown in Fig. 23.

Fig. 26 illustrates the access gained to the upper portions of the patient's left ventricle by rotating the inner catheter which includes the upper portions of the patient's interventricular septum.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1-3 schematically illustrates one presently preferred delivery system 10 of the invention with a distal portion thereof disposed within the left ventricle 11 of a patient's heart 12. The delivery system 10 includes a guiding catheter 13, a first delivery catheter 14 slidably and rotatably disposed within the inner lumen 15 of the guiding catheter and a second delivery catheter 16 which is slidably disposed within the inner lumen 17 of the first delivery catheter. An optical fiber 18 with a laser focusing lens 20 is slidably disposed within the inner lumen 21 of the second delivery catheter 16.

As shown in greater detail in Fig. 2, the guiding catheter 13 may be of conventional construction which includes a inner lubricous lining 22, a braided fiber reinforcement 23 and an outer jacket 24 which may be formed of suitable polymeric material in a conventional manner, e.g. extruding onto the braided fiber reinforcement. Suitable polymers include polyethylene, polyurethane and the like. The strands of the fiber reinforcement 23 may be stainless steel, or other suitable high strength materials including suitable polymeric materials. The lubricous inner liner 22 may be formed of a suitable fluoropolymer such as poly(tetrafluoro)ethylene which is sold under the trademark Teflon®. The overall length of the guiding catheter 13 is about 70 to about 110 cm, the outer diameter is about 0.1 to about 0.15 inch (2.5-3.75 mm) and an inner diameter of about 0.07 to about 0.1 inch (1.8-2.5 mm).

The first delivery catheter 14 is formed in a similar manner as the guiding catheter 13 except that the outer diameter of the first delivery catheter is configured so that it can be readily moved longitudinally and readily rotated within the guiding catheter by manipulating the proximal end which extends out of the patient. The overall length of the first delivery catheter 14 is about 10 to about 40

cm longer than the guiding catheter 13 to ensure that the distal end and the proximal end of the first delivery catheter extend out the distal end and the proximal end respectively of the guiding catheter so that movement of the distal end of the first delivery catheter can be effected by manipulation of the proximal end. A pair of radiopaque markers 25 and 26 are provided on the distal end 27 of the first delivery catheter 14 to allow the fluoroscopic observation thereof by the attending physician to determine the location and the orientation of the distal end within the patient's left ventricle 11.

The second delivery catheter 16 is an elongated polymeric tubular member which is formed of suitable thermoplastic polymers such as polyethylene, polyamide, polyether amide and polyurethane copolymer such as Pebax. The overall length of the second delivery catheter 16 is greater than the overall length of the first delivery catheter 14 to allow movement of the distal end 28 of the second delivery catheter 16 by manipulation of its proximal end which extends out the proximal end of the guiding catheter which in turn extends out of the patient. The length of the second delivery catheter 16 is typically about 10 to about 30 cm longer than the first delivery catheter 14. The outer diameter of the second delivery catheter 16 is about 0.002 to about 0.008 inch (0.05-0.2 mm) less than the inner diameter of the first delivery catheter 14 to facilitate relative movement between these two tubular members. The inner diameter of the second delivery catheter 16 is about 0.04 to about 0.06 inch (1-1.5 mm). A radiopaque band 30 may be provided on the distal end 28 of the second delivery catheter 16 to allow fluoroscopic detection of the distal end during the procedure.

When the distal end of the second delivery catheter 16 is closely adjacent to or in contact with the endocardium 31 which defines the left ventricle, the elongated optical fiber 18 is advanced out the port 32 in the distal end 28 of the second delivery catheter 16 to contact the

surfac of the endocardium 31. Laser energy is then directed through the optical fiber 18 out the lens 20 on the distal end of the optical fiber onto the endocardial tissue as shown in Fig. 4. The axial force applied to the proximal end of the optical fiber 18 is preferably sufficient to ensure contact with endocardial and myocardial tissue as the channel 33 is being formed therethrough, but the force should not exceed the level which will cause the optical fiber to mechanically penetrate heart tissue.

As shown in more detail in Fig. 6, the lens 20 on the optical fiber 18 has a cylindrical outer surface terminating in a convex distal tip 34. The distal end of the optical fiber 18 extends into the interior of the lens 20 and preferably terminates at a location proximal to the internal aspheric or ogival shaped surface 35 so as to be in a light transmitting relationship therewith. The distal end of the optical fiber 18 should be secured to the interior of lens 20 by suitable adhesive such as epoxy to prevent dislodgement of the lens when the device is disposed within the patient's body. Other lens constructions may be used. Generally, the overall length of the optical fiber 18 is longer than the second delivery catheter 16 and it is preferably configured to extend out of the second delivery catheter up to about 15mm, preferably about 1 to about 10 mm to form the channel 33. The outer diameter of the lens 20 generally will be essentially about the same size as the desired diameter of the channel, e.g. about 0.5 to about 2 mm, preferably about 1 to about 1.5 mm. The optical fiber 18 should have a diameter of about 0.2 to about 0.4 mm to provide the flexibility required to pass through the passageway of the second delivery catheter 16, but it may require support such as described in copending application Serial No. 07/873,964, filed on April 24, 1992, entitled "Shapeable Optical Fiber Apparatus", which is incorporated herein in its entirety by reference. Further details of the optical fiber and laser source may also be found in U.S. Patent 5,093,877 (Aita *et al.*), which is incorporated herein in its

entirety by reference. The optical fiber 18 may be a single fiber as describe above or a plurality of optical fibers.

The laser energy emitted from the lens 20 on the distal end of the optical fiber 18 may be emitted in a pulsatile manner ranging from about one to about 5 pulses or more during each heart beat. The energy level per pulse typically ranges about 0.5 to about 3 joules, preferably about 0.8 to about 2 joules. A higher laser energy level may be desirable when forming the channel in the endocardium than when forming the channel in myocardial tissue.

The universal movement of the distal ends of the first delivery catheter 14, the second delivery catheter 16 and the optical fiber 18 within the patient's left ventricle is illustrated in Figs. 1 and 5. The guiding catheter 13 is preferably maintained stationary with its distal end either closely adjacent to the side of the aortic valve 36 within the ascending aorta (not shown) or within the interior of the left ventricle 11 as shown in phantom in Fig. 1. If desired, the distal end of the guiding catheter 13 may be first inserted into the left ventricle where the first delivery catheter 14 is extended out the distal end of the guiding catheter and then withdrawn through the aortic valve 36 into the ascending aorta. The first delivery catheter 14 may be moved vertically within the heart chamber 11 by extending or withdrawing the catheter along the Z axis and be rotated about the Z axis as shown by angle θ on the circular projection 37. The deflection of the distal extremity of the first delivery catheter 13 from the Z axis, angle ϕ may be formed or adjusted manually before inserting the first delivery catheter into the patient or it may be adjusted after positioning within the heart chamber, e.g. by providing one or more control lines (not shown) extending through the catheter and secured to the distal end 28 thereof in a manner which is widely practiced with electrophysiological type catheters.. Once the first delivery catheter 13 is in a desired orientation

within the left ventricle, the second delivery cathet r may then be extended a distance r to contact the surface of the ndocardium 31.

The guiding catheter 13 and the first delivery catheter 14 are both constructed to be relatively stiff to prevent significant movement thereof when the optical fiber 18 is advanced within the heart chamber 11 during channel formation. If needed, mechanical elements (not shown) extending from the guiding catheter 13 or the first delivery catheter 14 may be utilized to engage the endocardium surface on a side opposite the channel forming site to bolster the position of these catheters during the procedure. The guiding catheter 13 may be shaped to ensure that the distal portion of the catheter is more or less centrally located within the ventricle 11 to allow complete rotation of the first delivery catheter within the heart chamber.

In a presently preferred method of the invention, the guide catheter 13 is first introduced into the patient's arterial system, preferably by means of the Seldinger technique, (e.g. the femoral artery) and advanced through the arterial system including the aorta until the distal end of the guide catheter is disposed at a desired location either within the left ventricle 11 or in the ascending aorta downstream from the aortic valve. The first delivery catheter 14, the second delivery catheter 16 and the optical fiber 18, or other channel forming device, may then be advanced together or sequentially through the guiding catheter into the left ventricle. The first delivery catheter 14 is advanced out of or withdrawn into the guiding catheter 13 (as shown in Fig. 5) to vertically position the distal end within the left ventricle 11 and rotated to direct the distal end of the first delivery catheter 14 to the desired region of the endocardium where the channel is to be formed. If the distal extremity of the first delivery catheter 14 is preshaped, the distal extremity forms the desired shape when exiting the guiding catheter 13. If m ans are provided to deflect the distal tip of the first delivery

catheter 14, the deflection means may be employed to shape the distal extremity after it exits the guiding catheter to direct the distal end of the first delivery catheter toward the desired location on the endocardium. The second delivery catheter 16 may be extended out the distal end 27 of the first delivery catheter 14 to engage the portion of the endocardium into which the channel 33 is to be formed. The location of the distal end of the second delivery catheter can be detected fluoroscopically by means of the radiopaque marker 30. The elongated channel forming device such as optical fiber 18 may then be advanced through the inner lumen 21 of the second delivery catheter 16 and out the port 32 in the distal end 28 thereof into the endocardium tissue to form the channel 33 therein. Preferably pressure is applied to the channel forming means so as to maintain contact with the endocardial and myocardial tissue when forming the channel 33 of a desired length. Once the channel is formed, the channel forming device may be withdrawn and repositioned within the left ventricle 11 to form a channel at another location within the patient's heart wall.

Figs. 7-9 illustrate another presently preferred embodiment which includes a first delivery catheter 40 which has a main section 41 and distal extremity 42. The distal extremity 42 has a proximal portion 43 extending away from the main section 41 at an angle ϕ' and a distal portion 44 which extends away from the proximal portion at an angle β and an angle γ. While these angles can vary from about 40° to about 140°, preferably about 60° to about 120°, typically they are about 90°. In the embodiment shown in Fig. 7, the distal portion 44 is essentially 180° from the distal portion 44 shown in Fig. 8. Optical fiber 18, which is slidably disposed within the inner lumen 46, extends out the port 47 in the distal end of the catheter 40. In this embodiment, if a positioning catheter is not used, the portion of the optical fiber 45 which extends

out of the distal end of the first delivery catheter 40 may b provided with reinforcement (not shown) on the exterior there f.

While the invention has been described herein in terms of a presently preferred embodiments involving the use of laser energy to form the channel in the heart wall, those skilled in the art will recognize that other channel forming devices may be employed. For example, a rotating auger type channel forming device 50 is shown in Fig. 10 which has a cutting head 51 with a spiral cutting edge 52 secured to the drive shaft 53 rotatably supported within the elongated housing 54. Another example is abrasive type channel forming device 60 as shown in Fig. 11 which has an enlarged bulbous tip 61 which has abrasive material thereon and which is secured to the drive shaft 62 rotatably supported within the elongated housing 63. Another embodiment is shown in Fig. 12 wherein the channel forming device 70 includes a circular cutting blade 71 which is connected to drive shaft 72. Fig. 13 depicts a channel forming device 80 which has a distal tip 81 which is resistively or inductively heated by conductors 82 and 83. The operating temperature of the distal tip 81 is maintained about 80° to about 110° C. which is sufficient to form the channel through the endocardium into the myocardium. A thermocouple or other temperature sensing device 84 may be imbedded into the distal tip 81 to determine the temperature thereof. The signal developed by the sensing device 84 may be used to control the electrical power to the distal tip 81 in a conventional manner. Fig. 14 illustrates yet another type of channel forming device 90 wherein a high velocity fluid jet 91 emitted from a discharge nozzle 92 in the distal end of inner tubular member 93 is employed to form the channel. In this embodiment, debris from the channel forming operation is aspirated away from the site through the annular lumen 94 between the inner tubular member 93 and the outer tubular member 95 to avoid passage of such debris into the aorta and ultimately into the arterial

system of the patient's brain which can result in a stroke or into the coronary artery system which can result in a myocardial infarct.

Reference is made to Fig. 15 which depicts another presently preferred embodiment of the invention disposed within a left ventricle which provides access to an even greater area of the endocardial surface. This embodiment includes an outer catheter 100 having a shaped distal section 101, a port 102 in the distal end of the catheter and an inner lumen 103 extending within the outer catheter to the port in the distal end. This embodiment also includes an inner catheter 104 slidably and rotatably disposed within the inner lumen 103 of the outer catheter 100 which has a shaped distal section 105, a port 106 in the distal end of the inner catheter and an inner lumen 107 extending therein to the port in the distal end. An optical fiber assembly 108 is slidably disposed within the inner lumen 107 of inner catheter 104. Additional details of the optical fiber assembly 108 can be found in copending application Serial No. 08/584,957, filed January 11, 1996, entitled CHANNEL FORMING DEVICE WITH PENETRATING LIMITER, assigned to the present assignee which is incorporated herein by reference in its entirety. The distal section 101 of the outer catheter 100 is at an angle with respect to the main shaft section 109 of the outer catheter of about 90° to about 180°, preferably about 135° to about 165°. The distal section 105 of the inner catheter 103 is at an angle with respect to the main shaft section 110 of the inner catheter of about 45° to about 180° , preferably about 60° to about 130°. The distal section 101 of the outer catheter 100 desirably orients the inner catheter 103 extending out the distal end of the outer catheter in the same direction as the axis of the heart chamber so that rotation of the inner catheter within the outer catheter points the distal section 105 of the inner catheter 104 in a generally perpendicular direction to the endocardium 111 defining the chamber. Longitudinal and rotational

movement of the inner catheter 103 provides access to a large region of the endocardium 111.

Figs. 17 and 18 illustrate a presently preferred embodiment wherein the outer catheter 100 is provided with a supereleastic metallic shaping member 112 to shape and support the distal section 101 of the outer catheter as shown. The pseudoelastic properties of the support member 112 allow the distal section 101 to be readily straightened to facilitate entry and advancement through the patient's vasculature, but when the distal section 101 is no longer restrained in the heart chamber, the stress induced martensite phase of the NiTi alloy transforms back to the austenite phase and the remembered shape. The shaped shaping member 112 causes the distal section 101 to take the shape remembered by the shaping member 112. The pseudoelastic properties at body temperature require that the metallic member be predominantly in the austenite phase at or below body temperature. Alternatively, the shaping member 112 may be in a martensite phase at body temperature with the curved memory of the austenite phase being activated by heating the shaping member by means of an electrical current or other means to raise the temperature of the metallic member to a temperature which is high enough to convert a predominant amount of the martensite phase to the austenite phase thereby causing the member to transform into the remembered curved shape. The preferred alloy is an equiatomic alloy of nickel and titanium. See for example the alloy compositions and thermomechanical processing described in U.S. Patent No. 5,341,818 (Abrams *et al.*) which is incorporated herein in its entirety by reference. The nickel-titanium alloys and thermomechanical processing described in this patent would be suitable to manufacture the shaping member 110 so as to provide pseudoelastic properties at body temperature.

Figs. 18-19 depict a distal section 101' suitable for the outer catheter 100 which is formed of a pseudoelastic alloy such as

described above. The distal section 101' has a plurality of transverse slots 113 in the outer curved portion thereof to facilitate bending without kinking. Longitudinal slots 114 may also be provid d along the side portion of the distal extremity 101' to further facilitate bending without kinking. As in the prior example, the distal section 101' may be formed of a shape memory alloy and be heated to the transformation temperature to generate the remembered shape. The alloy composition and thermomechanical processing is chosen to ensure that the transformation temperature is less than 100°C., preferably less than 85°C.

Fig. 20 illustrates placement of the outer catheter 100 within the patient's left ventricle so that the main shaft section 110 of the inner delivery catheter lies along the ventricular axis 115. In this position the inner catheter 103 can be moved longitudinally and rotationally to facilitate perpendicular or near perpendicular orientation of the optical fiber with the endocardial surface when the optical fiber engages the endocardium 111.

The embodiment shown in Fig. 21 depicts the distal extremity of the outer delivery catheter 100 in position against the interventricular septum 116l. This embodiment wherein the outer catheter 100 has a large angle, e.g. 140°-165° shown by the double point arrow 117 between the distal extremity 101 and the main catheter section 109, facilitates doubling back onto the interventricular septal wall 116 such as shown in Fig. 22. Another advantage of an outer catheter 100 with a large angle bend between the main catheter section 109 and the distal section 101, is shown in Figs. 23 and 24, is the ability to access the apical area 118 within the left ventricle which has been shaded, including the lower regions of the interventricular septum. The angle between the distal section 105 and the main section 110 of the inner delivery catheter 104 shown by double point arrow 119 can range

and which has proximal and distal ends, means on the distal end of the device to form a channel within the desired region of the endocardial layer of the patient's heart and a length greater than the second delivery catheter.

2. The system of claim 1 wherein the first delivery catheter is configured to move longitudinally along and rotationally about a longitudinal axis of the inner lumen of the guiding catheter in the distal extremity thereof.

3. The system of claim 2 wherein the second delivery catheter is configured to move longitudinally within the inner lumen of the first delivery catheter along its longitudinal axis and out the port in the distal end thereof so as to engage the desired region of the endocardial layer.

4. The system of claim 2 wherein the elongated channel forming device is configured to move through the inner lumen of the second delivery catheter and out the port in the distal end thereof into engagement with tissue of the endocardial layer.

5. The system of claim 2 wherein the distal extremity of the first delivery catheter is preshaped to deflect away from a longitudinal axis of the distal extremity of the guiding catheter so that the distal extremity of the first delivery catheter can be directed toward the desired region of the endocardial layer when the distal extremity of the first delivery catheter exits the distal end of the guiding catheter.

6. The system of claim 1 wherein the elongated channel forming device is an optical fiber optically connected to a source of laser energy.

7. The system of claim 1 wherein the elongated channel forming device has a heating means on its distal end.

8. The system of claim 1 wherein the elongated channel forming device has a tubular element connected to a source of high pressure fluid with an opening in the distal end thereof configured to form a fluid jet.

9. The system of claim 1 wherein the elongated channel forming device has a rotatable circular cutting blade on its distal end.

10. The system of claim 1 wherein the elongated channel forming device has a rotatable abrading number on its distal end.

11. The system of claim 1 wherein the elongated channel forming device has a rotatable cutting head with a spiral cutting edge on its distal end.

12. A method for forming a channel through an endocardial layer of a patient's heart defining a left ventricle from within the left ventricle, comprising:

a) introducing a guiding catheter into a peripheral artery of the patient;

b) advancing the guiding catheter through the patient's arterial system until a distal portion of the guiding catheter extends at least into an aortic passageway adjacent the patient's left ventricle;

c) advancing a first delivery catheter through the distal portion of the guiding catheter until a distal portion of the first delivery cathet r extends into the patient's left ventricle;

d) advancing a sec nd delivery catheter through the first delivery catheter until a distal portion of the second delivery catheter extends out the distal end of the first delivery catheter;

e) advancing an elongated channel forming device having an operative distal end through the second delivery catheter and out a port in a distal end of the second delivery catheter so that the operative distal end engages the desired region of the patient's endocardial layer; and

f) activating the channel forming device so as to form a channel through the endocardial layer and advancing the operative distal end within the channel as it is formed.

13. The method of claim 12 wherein the guiding catheter is advanced until the distal portion thereof extends into the patient's left ventricle.

14. The method of claim 13 wherein the location of the second delivery catheter is fluoroscopically determined by means of a radiopaque marker provided on the distal end of the second delivery catheter.

15. The method of claim 12 wherein the elongated channel forming device is an optical fiber and the channel is formed by laser energy emitted from a distal extremity of the optical fiber.

16. The method of claim 12 wherein the elongated channel forming device has an abrading member on its distal end and the channel is formed by rotating the abrading member.

17. The method of claim 12 wherein the elongated chann l forming device has a spiral cutting edge on its distal end and the channel is formed by rotating the distal end.

18. The method of claim 12 wherein the elongated channel forming device has a circular cutting blade having a distal serrated edge and the channel is formed by rotation of the circular cutting blade.

19. The method of claim 12 wherein the elongated channel forming device has a nozzle on the distal end and the channel is formed by omitting a high pressure fluid jet from the nozzle.

20. The method of claim 12 wherein the elongated channel forming device has a probe tip at an elevated temperature on the distal end there.

21. A system for percutaneously delivering an elongated channel forming device to a left ventricle of a patient's heart comprising:

a) a first delivery catheter which has proximal and distal ends, a port in the distal end, an inner lumen extending therein to and in communication with the port in the distal end and a distal portion shaped so as to be directed to a desired region of the patient's endocardial layer into which a channel is to be formed; and

b) a second delivery catheter which is longer than the first delivery catheter and which has proximal and distal ends, a port in the distal end, an inner lumen which extends therein to and in fluid communication with the port in the distal end of the second delivery catheter and which is configured to slidably receive an elongated channel forming device.

c) advancing an elongated channel forming device through the second delivery catheter and out a port in a distal end of the second delivery catheter so that an operative distal end thereof engages the desired region of the patient's endocardium; and

d) activating the channel forming device so as to form a channel and advancing the operative distal end within the channel as it is formed.

27. The method of claim 26 wherein a guiding catheter is first introduced into a peripheral artery of the patient and advanced through the patient's arterial system until a distal portion of the guiding catheter extends at least into an aortic passageway adjacent the patient's left ventricle and then the first delivery catheter is advanced through an inner lumen of the guiding catheter to the interior of the patient's left ventricle.

28. The method of claim 27 wherein the guiding catheter is advanced until the distal portion thereof extends into the patient's left ventricle.

29. The method of claim 26 wherein the channel forming device is an optical fiber and the channel is formed by laser energy passing through the optical fiber and being emitted from a distal extremity thereof.

30. The method of claim 26 wherein the channel forming device has a rotatable abrading member and the channel is formed by rotation of the abrading member.

31. The method of claim 26 wherein the channel forming device emits RF energy to form the channel.

32. The method of claim 26 wherein the channel forming device has a rotatable auger with a spiral cutting edge and the channel is formed by rotating the auger.

33. The method of claim 21 wherein the channel forming device is a circular cutting blade having a distal serrated edge and the channel is formed by rotating the circular cutting blade.

34. The method of claim 26 wherein the channel forming device is a nozzle and the channel is formed by emitting a high pressure fluid jet from the nozzle.

35. The method of claim 26 wherein the channel forming device has a distal probe tip and the channel is formed by urging the probe tip at an elevated temperature into contact with the endocardium.

36. A method for forming a channel through an endocardium of a patient's heart and into the myocardium thereof from within the left ventricle, comprising:

a) advancing a first delivery catheter through the patient's vasculature until a distal portion of the first delivery catheter extends into the patient's left ventricle;

b) advancing a second delivery catheter through an inner lumen extending within the first delivery catheter until a distal portion of the second delivery catheter extends out the distal end of the first delivery catheter;

c) advancing an elongated channel forming device through the second delivery catheter and out a port in a distal end of the second delivery catheter so that an operative distal end th reof engages a desired region of the patient's endocardium; and

d) activating the channel forming device so as to form a channel within the heart wall.

37. The method of claim 36 wherein a therapeutic or diagnostic agent is delivered into the channel formed.

38. The method of claim 36 wherein a guiding catheter is first introduced into a peripheral artery of the patient and advanced through the patient's arterial system until a distal portion of the guiding catheter extends at least into an aortic passageway adjacent the patient's left ventricle and then the first delivery catheter is advanced through an inner lumen of the guiding catheter to the interior of the patient's left ventricle.

39. A system for forming a channel in a desired region of a wall of a patient's heart, comprising:

a) a first delivery catheter which has proximal and distal ends, a port in the distal end, an inner lumen extending to and in communication with the port in the distal end, an elongated proximal section with a longitudinal axis and a distal extremity which is shorter than the proximal section, which is shaped so as to be directed toward the desired region of the wall into which a channel is to be formed and which includes a proximal portion having a longitudinal axis and extending at an angle of about 50° to about 130° from the longitudinal axis of the proximal section

and a distal portion which is at an angle of about 50° to about 130° from the longitudinal axis of the proximal portion; and

b) a channel forming member slidably disposed within the inner lumen of the first delivery catheter and configured to have a distal operative end extend out of the port in the distal end of the first delivery catheter.

40. The system of claim 39 wherein the channel forming member is an optical fiber which is optically connected to a laser source.

41. A system for percutaneously delivering an elongated therapeutic or diagnostic device into a chamber of a patient's heart comprising:

a) a first catheter which has proximal and distal ends, a port in the distal end, an inner lumen extending therein to and in communication with the port in the distal end, a main shaft portion a relatively short shaped distal portion having an exit axis which is at an angle of at least 30° from the main shaft portion; and

b) a second catheter which is slidably disposed within the inner lumen of the first catheter,

which is longer than the first catheter, and

which has proximal and distal ends, a port in the distal end, an inner lumen configured to slidably receive an elongated therapeutic or diagnostic device and extending therein to and in fluid communication with the port in the distal end of the second catheter, a distal extremity of the second catheter having an exit axis at an angle of at least 30° from the exit axis of the first catheter.

42. The system of claim 41 including a guiding catheter having an inner lumen configured to slidably receive th first catheter and to facilitate longitudinal movement along and rotational movement about a longitudinal axis of the inner lumen of the guiding catheter.

43. The system of claim 41 wherein the second catheter is configured to move longitudinally within the inner lumen of the first catheter along its longitudinal axis.

44. The system of claim 41 wherein the revascularization device is configured to move longitudinally out of the inner lumen of the second catheter into tissue of the endocardium to form the channel.

45. The system of claim 42 wherein the distal extremity of the second catheter is shaped to deflect toward a portion of the endocardium in which the therapeutic or diagnostic procedure is to be performed when the distal extremity extends out the distal end of the guiding catheter.

46. A catheter system for delivery of therapeutic or diagnostic devices into a chamber of a patient's heart, comprising:

a) a first delivery catheter which has proximal and distal ends, a port in the distal end, an inner lumen extending to and in communication with the port in the distal end, a main catheter shaft section, an elongated distal extremity with an exit axis extending out of the port in the distal end at an angle of at least about 30° from the proximal section and

b) a second delivery catheter slidably disposed within the inner lumen of the first delivery catheter which has proximal and distal ends, a port in the distal end, an inner lumen extending

to and in communication with the port in the distal end which is configured to slidably receive an elongated therapeutic or diagnostic device and a distal extremity with an exit axis extending out of the port in the distal end thereof at an angle of at least about 30° [to about 130°] with respect to the exit axis of the first delivery catheter.

47. The catheter delivery system of claim 46 wherein the second catheter is a positioning catheter which has an exit axis which is at an angle of at least 150° with the exit axis of the first catheter.

48. The catheter delivery system of claim 46 including an elongated therapeutic or diagnostic device which is slidably disposed within the inner lumen of the second delivery catheter and which is configured to have a distal operative end extend out of the port in the distal end of the second catheter.

49. The system of claim 48 wherein the elongated therapeutic or diagnostic device is an elongated channel forming device.

50. The system of claim 49 wherein the elongated channel forming member is an optical fiber which is optically connected to a laser source.

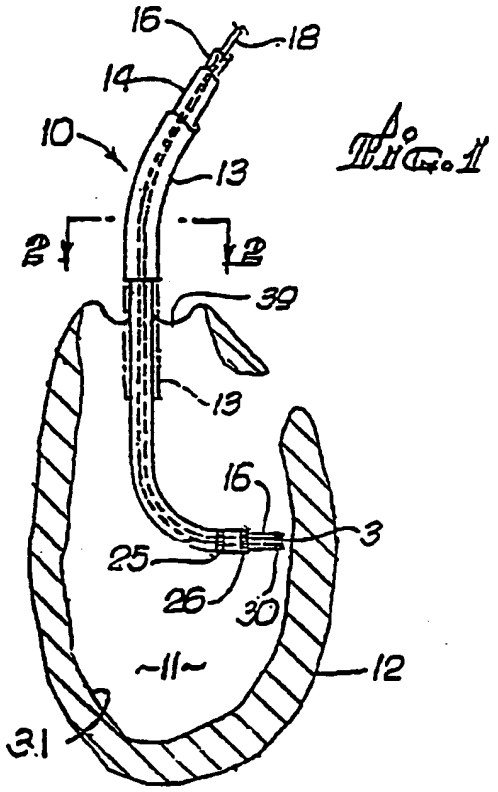


Fig. 1

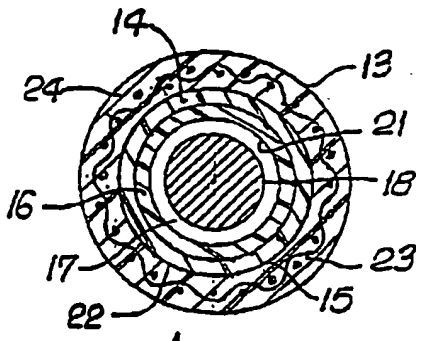


Fig. 2

Fig. 3

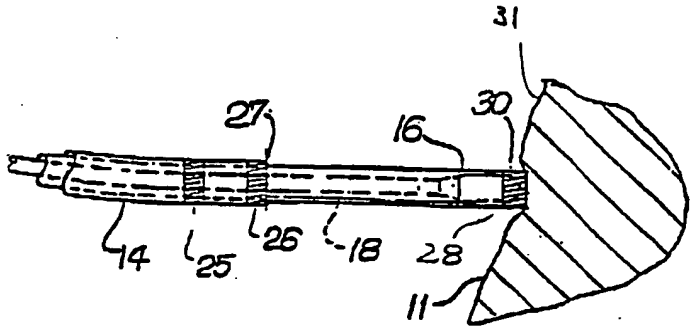


Fig. 4

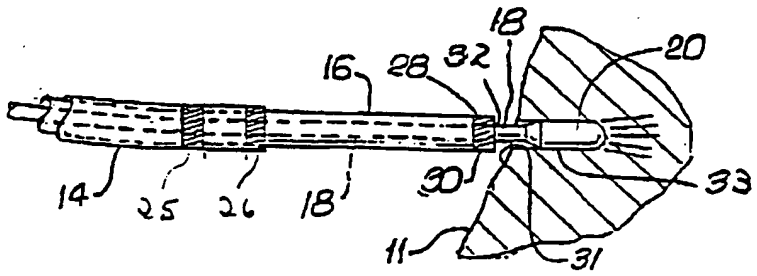


FIG. 5

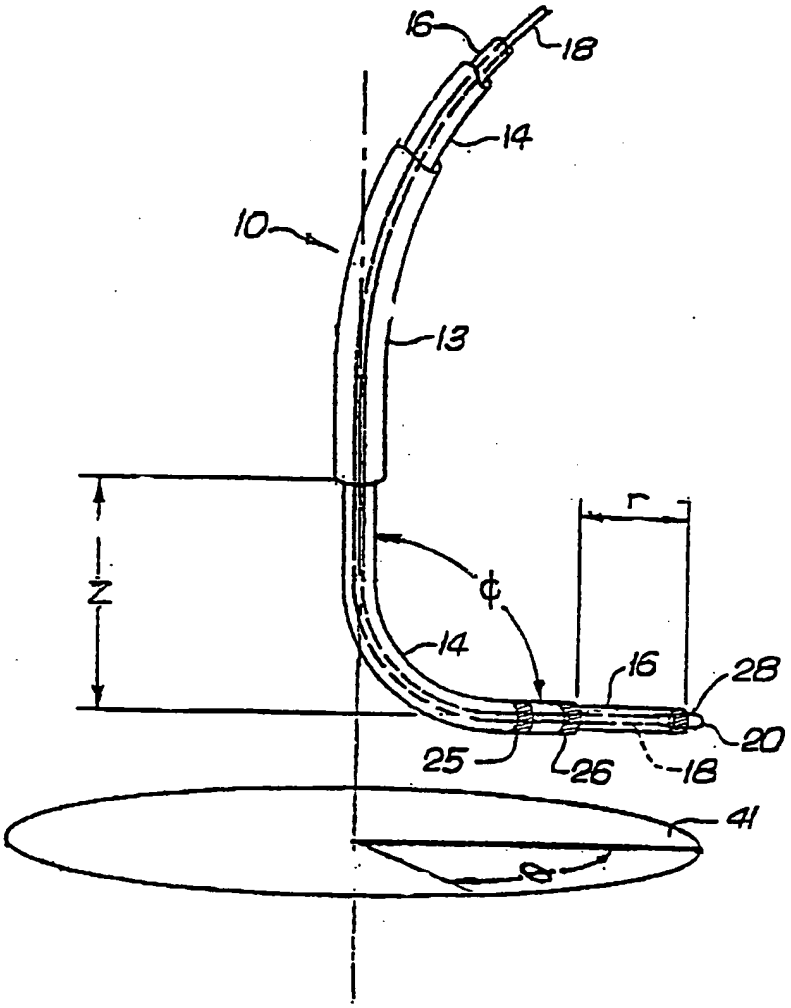


Fig. 6

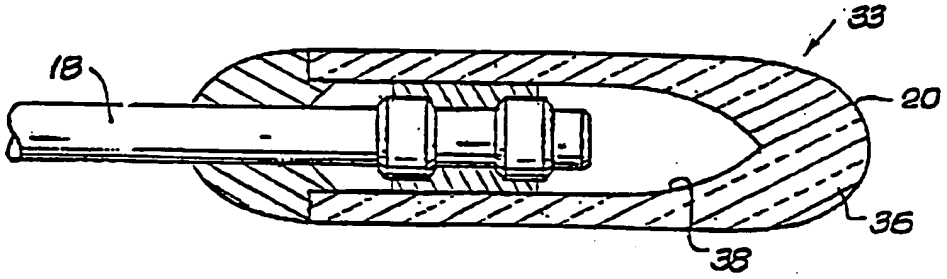


Fig. 10

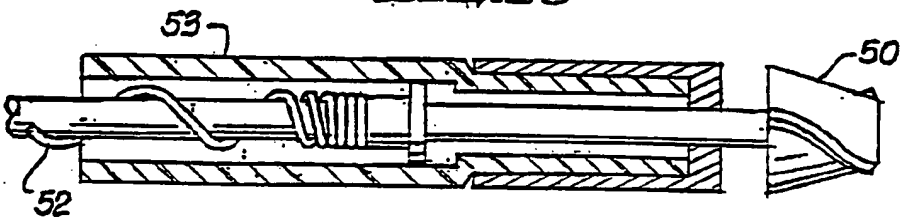


Fig. 11

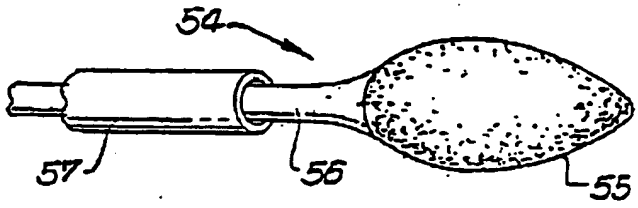


Fig. 7

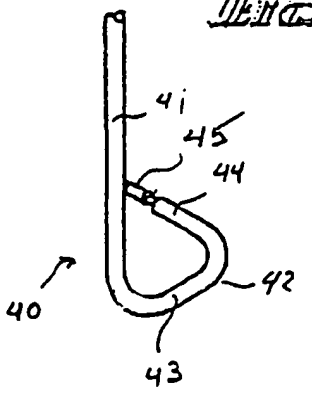


Fig. 8

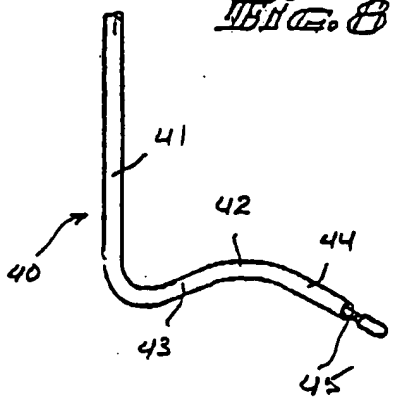


Fig. 9

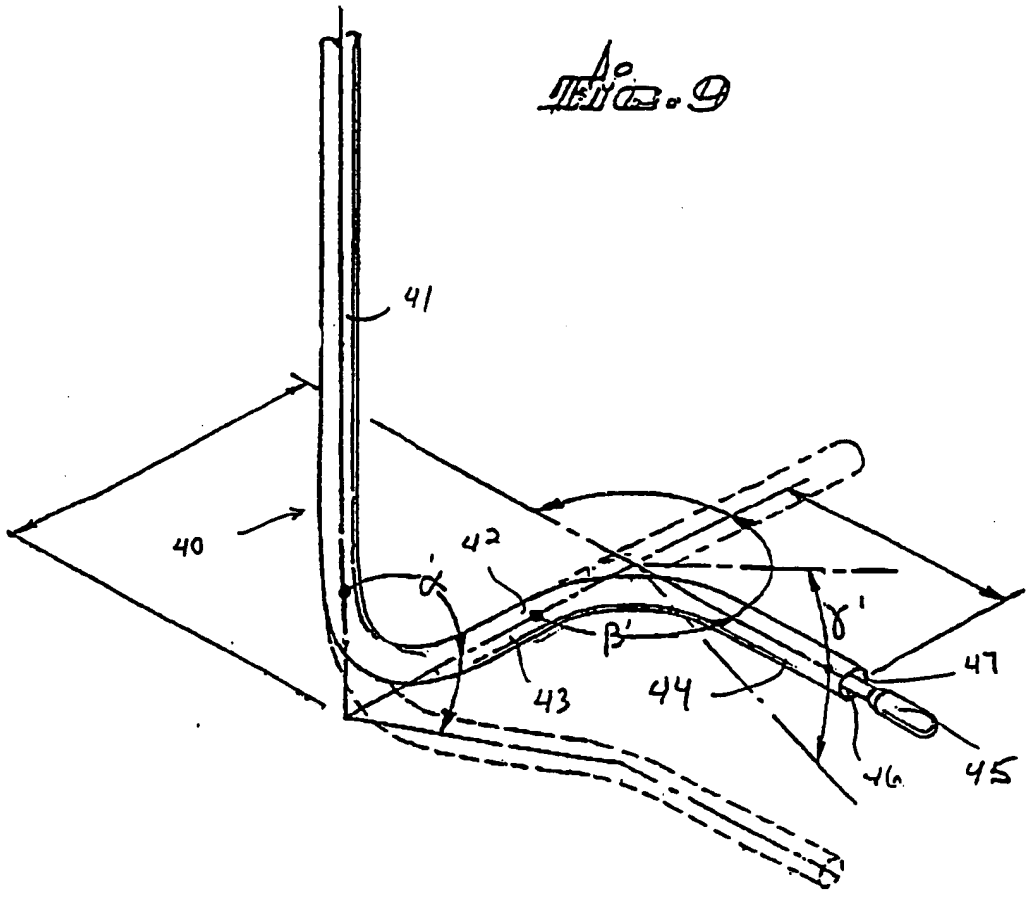


FIG. 12

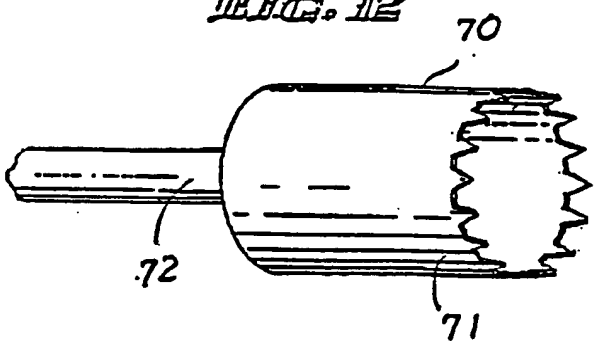


FIG. 13

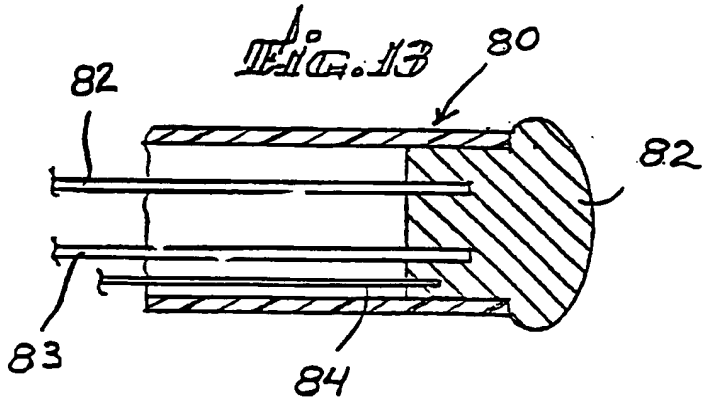
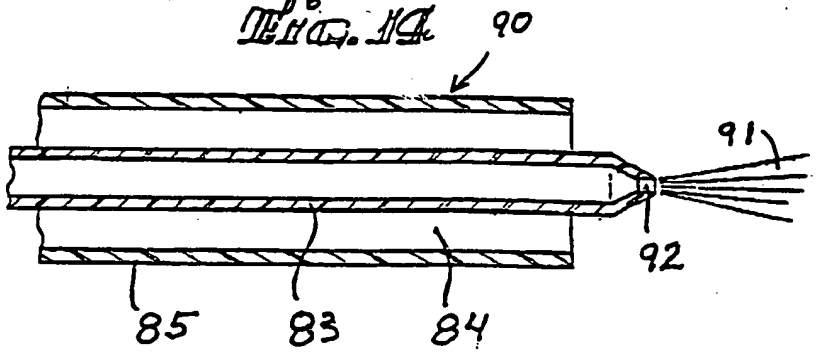


FIG. 14



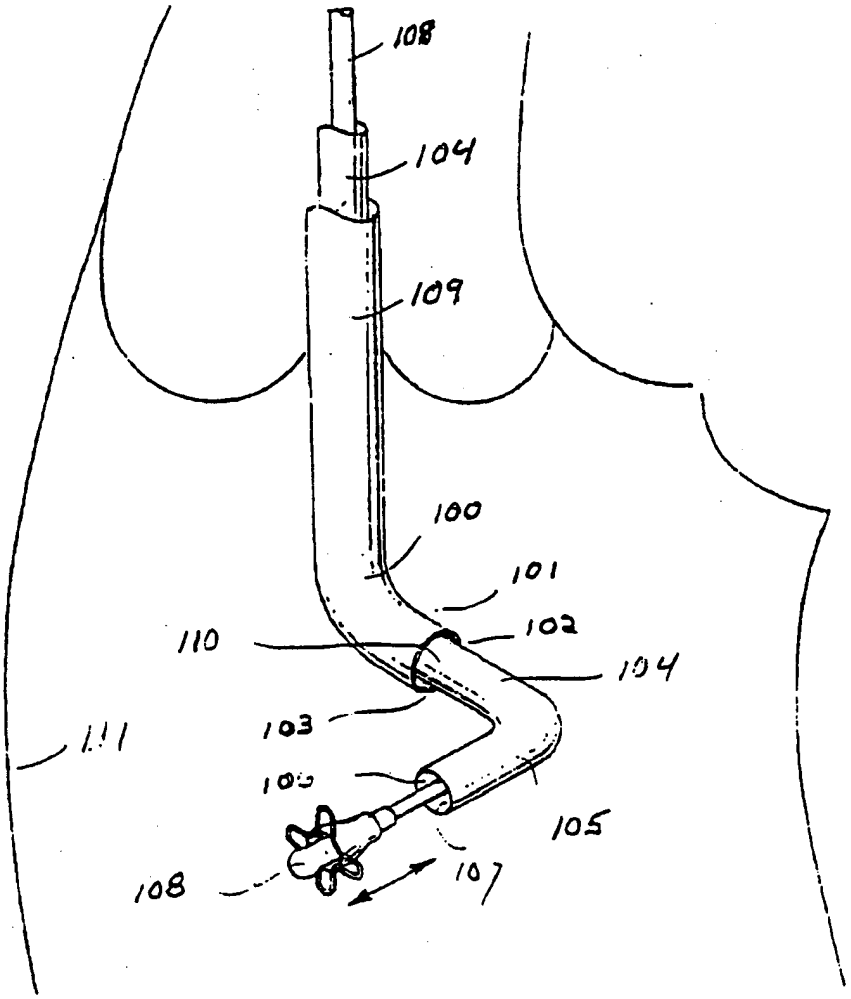


FIG. 15

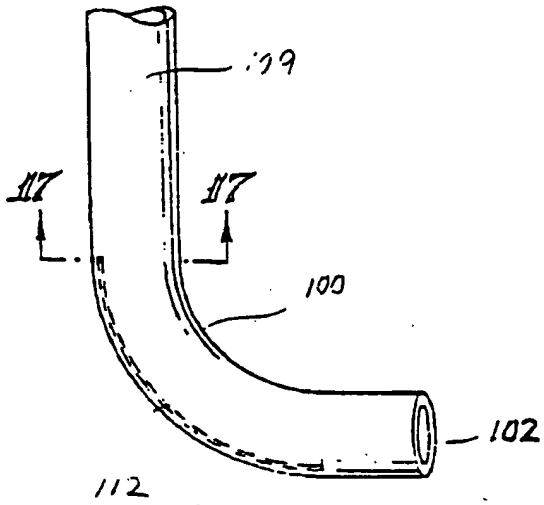


Fig. 16

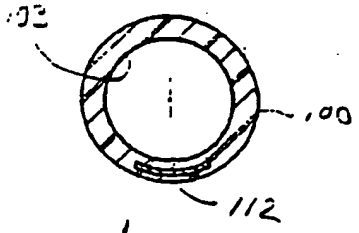


Fig. 17

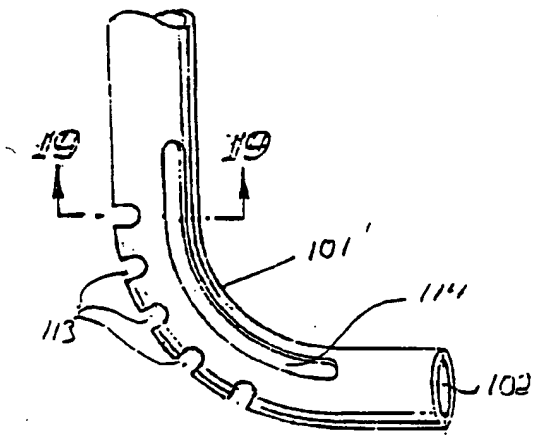


Fig. 18

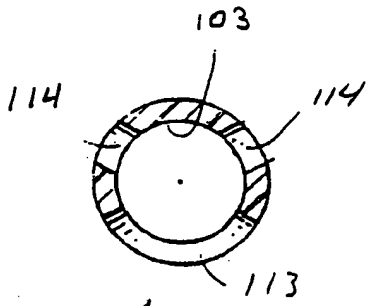


Fig. 19

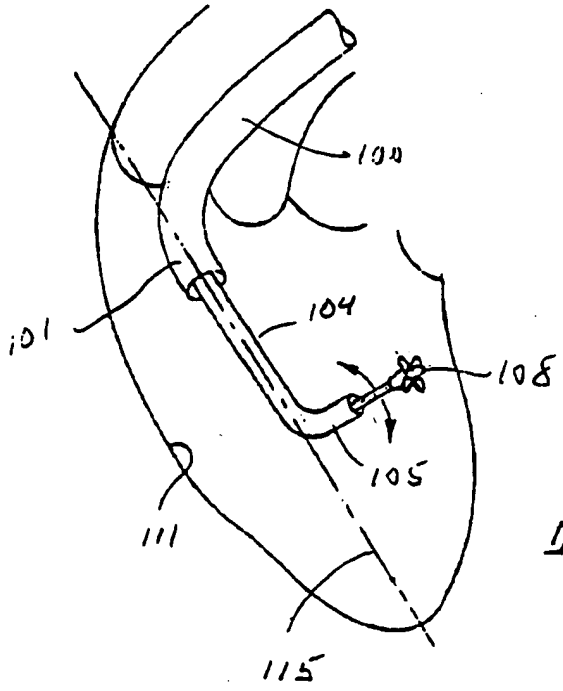


FIG. 20

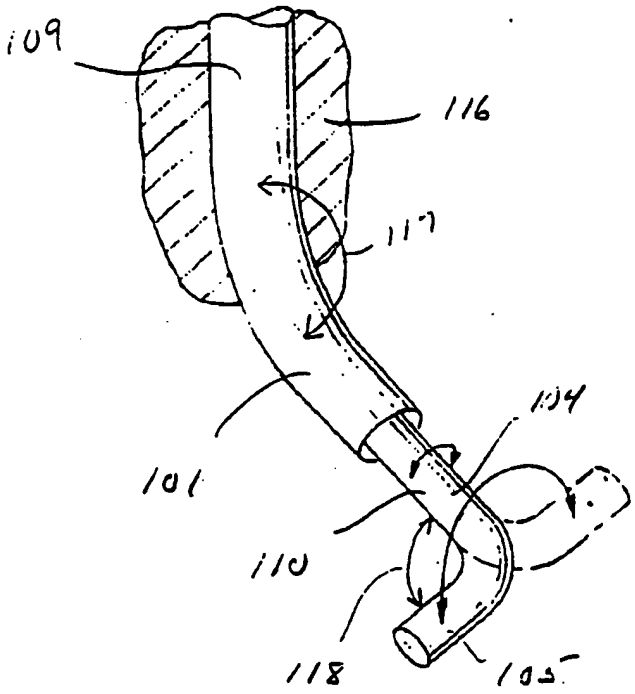


FIG. 21

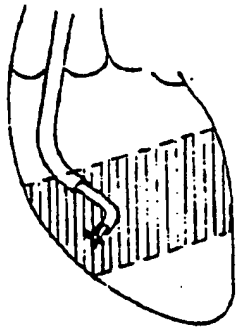


FIG. 22

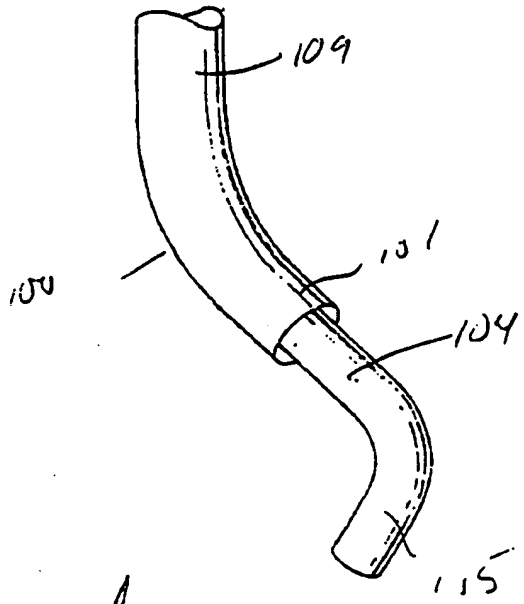


FIG. 23

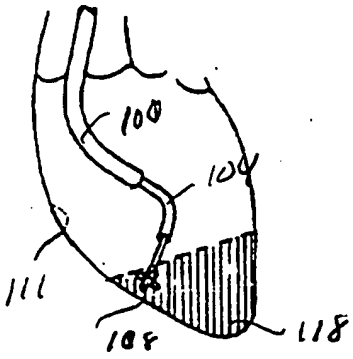


FIG. 24

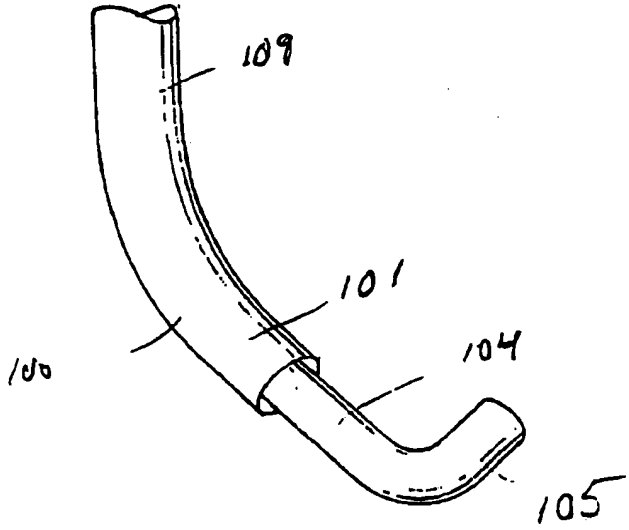


FIG. 25

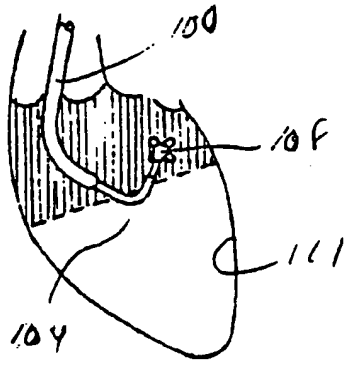


FIG. 26

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 96/06700

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61B17/36 A61B1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,92 12754 (VODA) 6 August 1992 see the whole document ---	39
Y	EP,A,0 277 366 (ADVANCED CARDIOVASCULAR) 10 August 1988 see column 7, line 36 see column 6, last paragraph; claim 1; figure 1 ---	1-50
Y	EP,A,0 515 867 (COLUMBIA UNIVERSITY NY) 2 December 1992 see abstract ---	1-50
A	WO,A,95 08364 (STANFORD) 30 March 1995 see page 34, paragraph 1 - paragraph 2; figures 11A,1B,1C --- -/--	1,21,39, 41,46

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 August 1996	05. 09. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Barton, S

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INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 96/06700

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,94 02077 (ANGELASE) 3 February 1994 see page 5, last paragraph - page 6, paragraph 1; figure 1	1-6, 21-25, 39-46
A	EP,A,0 448 859 (SHIBER) 2 October 1991 see column 4, paragraph 2; figures 1-4,7 see column 5, last paragraph	7-11
A	DE,U,295 01 973 (PEIN) 6 April 1995 see figure 1	8
A	EP,A,0 416 793 (ANGEION) 13 March 1991	
P,X	EP,A,0 670 168 (DAIG) 6 September 1995 see the whole document	39

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

rnational application No.
PCT/US 96/06700

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12-20, 26-38
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39. (iv)

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. nal Application No
PCT/US 96/06700

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .onal Application No
PCT/US 96/06700

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